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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte THOMAS E. TARARA, JEFFRY G. WEERS,
ALEXEY KABALNOV, ERNEST G. SCHUTT, and
LUIS A. DELLAMARY

Appeal 2010-010750
Application 09/886,296
Technology Center 1600

Before TONI R. SCHEINER, ERIC GRIMES, and
JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to compositions comprising particulate microstructures. The Examiner has rejected the claims for obviousness, indefiniteness, and obviousness-type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We reverse the obviousness and the indefiniteness rejections, and affirm the double patenting rejections.

STATEMENT OF THE CASE

The Specification discloses "perforated microstructures which comprise an active agent" (Spec. 1: 15). The Specification discloses that "the use of relatively low density perforated (or porous) microstructures … provides for superior aerodynamic performance when used in inhalation therapy" (*id.* at 5: 18-22).

Claims 57, 59-80 and 82-102 are on appeal. Claim 57 is representative and reads as follows:

> 57. An inhaleable powder composition comprising a plurality of particulate microstructures, the particulate microstructures comprising:
> (a) a structural matrix comprising phospholipid and calcium, wherein the particulate microstructures comprise greater than about 50% phospholipid;
> (b) an active agent;
> (c) a mean geometric diameter of 1-30 microns;
> (d) a mean aerodynamic diameter of less than 5 microns; and
> (e) a bulk density of less than about 0.5 g/cm^3.

Claim 80, the only other independent claim, similarly requires that "greater than about 50% of the particulate microstructures comprise phospholipid."

The claims stand rejected as follows:

- Claims 57, 59-80, and 82-102 under 35 U.S.C. § 112, second paragraph;
- Claims 57, 59-77, 80, and 82-100 under 35 U.S.C. § 103(a) as being obvious in view of Hanes,[1] Papahadjopoulos,[2] and Mori[3];

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[1] Hanes et al., US 5,855,913, issued Jan. 5, 1999.

• Claims 78 and 101 under 35 U.S.C. § 103(a) as being obvious in view of Hanes, Papahadjopoulos, Igarashi,[4] and Mori;

• Claims 79 and 102 under 35 U.S.C. § 103(a) as being obvious in view of Hanes, Papahadjopoulos, Benson,[5] and Mori;

• Claims 57, 59-80, and 82-102 for obviousness-type double patenting (i) in view of claims 1-3, 8, 9, 11-15, 17, 19-25, 29-32, 53-55, 57-62, and 64-89 of Application No. 09/851,226 (now US Patent 7,442,388) and (ii) provisionally, in view of claims of 6, 7, 9, 10, 46-50, 54-57, 59, 61-67, 69, 70, 74-77, and 79-90 of Application No. 09/568,818.[6]

I.

The Examiner has rejected claims 57, 59-80, and 82-102 under 35 U.S.C. § 112, second paragraph, on the basis that the phrase "greater than about 50%" is indefinite (Answer 6). The Examiner reasons that the term "'greater than'" is "a minima [sic] and all possible values above 50% are encompassed. 'About' indicates a range centered on the recited value.... Therefore, what values are included in the range 'greater than about 50% phospholipid' cannot be determined." (*Id.*)

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[2] Papahadjopoulos et al., *Cochleate Lipid Cylinders: Formation By Fusion Of Unilamellar Lipid Vesicles*, 394 BIOCHIMICA ET BIOPHYSICA ACTA 483-491 (1975).
[3] Mori et al., US 5,776,488, issued July 7, 1998.
[4] Igarashi et al., US 4,201,774, issued May 6, 1980.
[5] Benson et al., US 5,006,343, issued Apr. 9, 1991.
[6] Claims 57, 59-80 and 82-102 were also provisionally rejected for obviousness-type double patenting in view of Applications 10/750,934 and 10/982,191. These applications are now abandoned, and thus these rejections are moot.

Appellants argue that "the range of 'about' would be clear to one of ordinary skill in the art from the context of the specification…. [I]t follows that the range of 'greater than about' is also clear since it includes everything that is 'about 50%' and everything that is greater than that." (Appeal Br. 6.)

We agree with Appellants' position. The Examiner has not provided any basis for concluding that "about 50%" is indefinite, and "greater than" simply requires more than the minimum amount encompassed by "about 50%". The rejection under 35 U.S.C. § 112, second paragraph, is reversed.

II.

The Examiner has rejected all of the claims on appeal under 35 U.S.C. § 103(a) in view of Hanes, Papahadjopoulos, and Mori, by themselves or combined with Igarashi or Benson. The dispositive issues are the same for all three rejections, and thus we will consider them together.

The Examiner finds that Hanes discloses "aerodynamically light particles for drug delivery to the pulmonary system" with the dimensions recited in claims 57 and 80 (Answer 6). The Examiner finds that Hanes discloses that the "particles contain surfactants such as DPPC … and the microstructures are taught to encapsulate active agents" (*id.* at 7).[7] The Examiner further finds that Hanes discloses that "DPPC is a zwitterionic lipid and is present in an amount of 62.8 wt.% and 89.1 wt.% in Table 4 of Hanes" (*id.*). The Examiner finds that Papahadjopoulos discloses "adding calcium to fuse phospholipids including the phospholipids taught by Hanes into larger vesicles" (*id.* at 8). The Examiner concludes that it "would have been obvious to one of ordinary skill in the art … to combine the teachings

[7] DPPC is dipalmitoylphosphatidylcholine (Hanes, col. 3, ll. 61-62).

of Hanes and Papahadjopoulos and utilize calcium … to provide the desired lipid vesicles size" (*id.* at 8-9).

Appellants contend that the Examiner erred in finding that Hanes discloses "a particulate microstructure comprising greater than about 50% phospholipid" (Appeal Br. 14). Appellants argue that Table 4 of Hanes does not disclose particles that comprise greater than 50% phospholipid because the "62.8 and 89.1 referred to by the Examiner are not weight percents, but are DPPC loads in µg/mg spheres" (Appeal Br. 7).

The Examiner responds that Hanes' Example 2 "teaches spray-dried particles comprising 80 wt.% polymer and encapsulated 20 wt.% drug (testosterone)" (Answer 21). The Examiner reasons that "[s]ince Hanes also teaches particles that can consist solely of drug and surfactant and that drug can be encapsulated within the surfactant…, it would be within the skill of an artisan to substitute the 80 wt.% polymer for 80 wt.% surfactant in the drug encapsulated particles of Hanes' example 2" (*id.*).

We agree with Appellants that the Examiner has not adequately shown that the cited references would have made obvious the claimed particulate microstructures that comprise "greater than about 50% phospholipid." First, we agree with Appellants that the Examiner erred in finding that Hanes' Table 4 discloses particles comprising 62.8 and 89.1 weight percent DPPC, because the relevant column in that table is headed "DPPC Load (µg/mg spheres) and Efficiency (%)" and therefore does not indicate weight percent DPPC.

Second, we cannot agree with the Examiner's alternative rationale: that it would have been obvious to substitute surfactant for the polymer in

Hanes' Example 2 particles. Hanes discloses that its "particles incorporating a surfactant on the surface thereof" and "may be formed of biodegradable materials such as biodegradable polymers.... Alternatively, the particles may be formed solely of the drug or diagnostic agent and a surfactant" (Hanes, abstract).

Hanes exemplifies particles formed from several different materials (Hanes, cols. 11-13) but does not exemplify particles formed solely of a drug and a surfactant. The Examiner points to Hanes' Example 2 as describing particles containing 80% polymer and reasons that it would have been obvious to substitute surfactant for the polymer in those particles (Answer 21). However, the particles in that example are made of D,L-lactic-co-glycolic acid (PLGA) (Hanes, col. 11, ll. 60-64), and the Examiner has provided no basis for concluding that a skilled worker would have recognized a surfactant like DPPC to be functionally equivalent to the PLGA in Hanes' Example 2 particles.

The Examiner also has not provided persuasive reasoning to show that it would have been obvious to include greater than 50% surfactant (phospholipid) in Hanes' particles that are composed of only surfactant and active agent. In our view, Hanes' disclosure does not support such a conclusion. Although Hanes discloses that the "surfactant may be incorporated throughout the particle and on the surface during particle formation, or may be coated on the particle after particle formation" (*id.* at col. 5, ll. 18-20), it does not expressly disclose any particles that contain 50% surfactant. On the contrary, the only surfactant-containing particles exemplified by Hanes contained 62.8 and 89.1 μg/mg surfactant, which

would be equivalent to roughly 6.3 and 8.9% surfactant in the particles (Hanes, col. 18, ll. 35-47). Hanes does exemplify particles formed solely of an active agent, specifically lysozyme,[8] but provides no reason to include at least 50% surfactant in the particles. Rather, Hanes discloses that the advantages conferred by a surfactant are due to the presence of surfactant on the surface of the particles (Hanes, col. 5, ll. 26-37). That is, Hanes appears to suggest that particles formed solely of surfactant and agent would contain the active agent, not surfactant, as the predominant particle forming component.

The rejections under 35 U.S.C. § 103(a) are reversed.

III.

The Examiner has rejected claims 57, 59-80, and 82-102 for obviousness-type double patenting in view of the claims of Application No. 09/851,226 (now US Patent 7,442,388) and for provisional obviousness-type double patenting in view of the claims of Application No. 09/568,818. Appellants do not dispute the obviousness-type double patenting rejections, but note that they "will file terminal disclaimers as appropriate upon the indication of otherwise allowable claims" (Appeal Br. 17). Since Appellants have not disputed the merits of the obviousness-type double patenting rejections, they are summarily affirmed.

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[8] Hanes discloses that the lysozyme retained enzymatic activity after being formed into particles by spray drying (Hanes, col. 12, ll. 38-40); thus, the lysozyme appears to have been intended to be an active agent.

SUMMARY

We affirm the rejection of claims 57, 59-80, and 82-102 for obviousness-type double patenting. However, we reverse the rejections of claims 57, 59-80, and 82-102 under 35 U.S.C. § 103(a) and under 35 U.S.C. § 112, second paragraph.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

cdc